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IMPLEMENTING AN ISO 9001 MANAGEMENT SYSTEM IN PROCESSES OF ADDITIVE MANUFACTURING FOR MEDICAL USE

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ABSTRACT

Based on a case study, this paper presents a methodology to adopt ISO 9001 standards for organizations, which make use of additive manufacturing to build products for medical use. Starting with a conceptual model, guidelines were identified to guide planning and operation of the management system, as well as its maintenance and improvement.

Keywords: ISO 9001; Quality Systems; Additive Manufacturing

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1. INTRODUCTION

In the last decade we have witnessed a major breakthrough in technological innovation, especially with regard to the emergence of new products and services being made available to the consumer, and this has become increasingly demanding. Given this statement, organizations are faced with the need to implement or even optimize quality management systems. Thus, a technological modernization must be performed with criteria, adding value to processes that comprise each organization to achieve a continuous improvement of its products / services.

In this context, the modernization of production processes, the Additive Manufacturing (AM) process by which objects are created in three dimensions, using CAD software (Computer-Aided Design), and print 3D printers, has revolutionized the world market, bringing numerous benefits to companies and organizations that have implemented this technology in its process (VOLPATO, 2007).

Thus, with the purpose of standardizing the entire production process, including the MA, the Quality Management System (QMS) ISO 9001 series seeks to provide confidence to stakeholders, especially customers, and denotes the certification bodies which the company manages the quality, aiming to fully meet the standard requirements (CARPINET, MIGUEL and GEROLAMO, 2007).

Second Meulen and Rivera (2014), the year 2015 will be a milestone in labor relations between man and machine, where more than 90% of the producers of durable goods will actively pursue external partnerships to support new business models customized products, and by 2017, approximately 20% of these will use 3D printing to meet the demands of the market.

Historically, demand for products and services with fast delivery, low cost and adaptable to consumer needs, are encouraging a revolution of the manufacturing market. Within this reasoning, the use of 3D printing has caused a profound impact on the viability of new businesses by reducing production costs. All categories of durable goods feel the need to customize the product made possible by increasingly easy access, and the trend is for manufacturers to develop ways to bring consumers closer to the project development experience.

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Traditionally, MA is best known in the areas of industrial production, construction and architecture, but its use in the medical field has been widespread since the 90s, when their application was extended for the manufacture of custom implants and prostheses, Anatomy of study and surgical plans in cases of trauma or squeals. (BERTOL, 2008).

This article aims to present through case study, a methodology to adapt the ISO 9001 standards for additives manufacturing organizations for printing products for medical use.

2. THEORETICAL FOUNDATION

2.1 ISO 9001

The Quality Management Systems (QMS) are an interesting alternative to optimize processes in organizations as they develop a pattern of improvement from the motivation of the workforce, the process control, identifying requirements and meeting the needs clients (CALARGE; LIMA, 2001).

It is appropriate that the adoption of a quality management system is a strategic decision of an organization. So we use the ISO 9001:2008 to promote the adoption of a process approach when developing, implementing and improving the effectiveness of a management system looking for customer satisfaction by meeting customer requirements (ABNT, 2008), establishing which the quality policy of an organization, as well as its quality manual where procedures, objectives, indicators and internal and external audit cycles should be described.

This pattern of adoption of ISO 9001 applies, at least in theory, to all organizations, regardless of type, size or product / service offered and can be considered a basic and introductory element to establish structured and organized process, making it the fundamental basis for the advancement of quality and hence of business management (MAEKAWA ; CARVALHO; OLIVEIRA, 2013).

As Magd (2008), the most important perceived benefits with the implementation of ISO 9001 in organizations are improved documentation, quality system efficiency; clear statement of work, procedures and responsibilities (aid in the selection of suppliers and product quality).

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The form is used to demonstrate the quality of the production process is the certification, which is issued by an institution accredited by INMETRO. The ISO certification was created to prove the quality standard of a company, also used as a way to avoid waste, increase productivity and efficiency and provide a higher level of internal organization of the company. (MIRANDA et al., 2006). External certification bodies carry out certification of an organization, since the ISO itself cannot issue certificates.

2.2 Additive Manufacturing applied to Health

The technologies applied strategically in health have played key role in the contemporary world, creating increasingly frequent search update from professionals with regard to the areas of technological innovation (CASTELO BRANCO, 2014). As a concrete example of this innovation is the three-dimensional printing.

The rapid prototyping term has been replaced by Additive Manufacturing since 2010, a technical committee formed by the American Society for Testing and Materials (ASTM) agreed that a new technical term should be adopted. The purpose of this new nomenclature is clear that some machines with this technology can be built to final objects from templates generated in CAD (NASCIMENTO, 2013).

The MA process involves high technology and complexity, since alloy materials, layer by layer, in order to construct an object, called biomodel, in health care (GORNI, 2007).

The acquisition of bio models compatible with the human anatomy has been developed due to the integration of CAD technology to technological advances in medical imaging. This integration enables images Computed Tomography (CT), Magnetic Resonance Imaging (MRI), ultrasound (US) or 3D Scanner properly saved in DICOM (Digital Imaging and Communications in Medicine) are processed by specific programs, creating a together dimensional (3D) data in .STL format (Stereolithographic), sent to the stations Rapid Prototyping (RP) where, through the CAM system (Computed Aided Manufacturing), the bio models are manufactured (SUGAR et al,. 2004).

Currently, there are many efforts in order to reduce more and more mistakes and / or secondary issues in medical surgeries, since the results obtained these must be the most accurate possible. Therefore, a set of information is needed before

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this procedure, and an accurate clinical examination, laboratory tests and imaging to be no complications in bringing further damage to the patient. Thanks to the additive manufacturing technology, a complete surgical planning is possible by studying the three-dimensional model to simulate the possibility of still making the surgical procedure more realistic (GIROD et al., 2001). A large area that has benefited from additive manufacturing is to the maxillofacial complex surgeries (SAFIRA et al., 2010)

Another major use for this technology is in the manufacture of molds for custom prostheses used in reconstructive surgery of bony parts to repair congenital deformities or trauma of any part of the body (BERTOL, 2008).

Among all the advantages cited in the use of Additive Manufacturing can cite independence in geometric complexity of any piece because the component is manufactured in a single process step built into a single unit from start to finish, it is carried out almost automatically by and dedicated systems is still done in less time and at lower cost, and can also be made in large quantities (VOLPATO, 2007).

2.3 ISO 9001 in Additive Manufacturing environments for medical use

The adoption of quality management systems in environments that use the Additive Manufacturing process is reduced, we can mention the few that exist, this happens because it is a new technology and which is on the rise (AHRENS et al., 2012). However, when we speak only in the medical field as a whole, we can mention hospitals, clinics, laboratories and many other environments that have ISO 9001 certification, as they have to present a standard of excellence to put on the market (MIRANDA; ALMEIDA, 2007).

When we set off for environment specifically work with Additive Manufacturing, we have difficulty, the AM process is not yet fully finalized, as there are many applications in the medical, industrial, civil, bioengineering, among others, and each area uses a method differentiated process, thus difficult to standardize. But it is already publicly known certification of dimensional Technologies Division (DT3D) of the Information Renato Acher Technology Center (CTI) to ISO 9001, which was the subject of this study.

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3. METHODOLOGY

3.1 Type of Study

This study is characterized as a descriptive research, the case study type, through interviews.

According to Cervo et al (2007), descriptive studies, observe, register, analyzes and correlates collected facts of reality itself. According to Barros and Lehfeld (2000), case studies turns to the collection and registration information on one or more individualized cases, developing critical reports organized and evaluated, giving margin to decisions and interventions on the chosen object for research, which can be a community, an organization, a business, etc. Cervo et al (2007) also reports that data collection involves several steps such as preparing the collection instrument, the schedule of collection and also the type of data and collection.

Taking theoretical basis for these claims, this case study was conducted through interviews and monitoring of the organization's activities. A research screenplay was elaborate from data collected from the guidelines governing the ISO 9001: 2008. Contains questions related to the items of this standard and even some made by the authors in order to extract information about the implementation of the quality management system as well as the impacts, benefits and achievements of the organization chosen for this study. This script can be seen in the table 1:

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Table 1 - Screenplay interview Case Study

Interview script	
Organization Profile	Name
	Start up date
	Location
	Industry/playing field
	No of employees
Certification Scope	Standard adopted
	Product line(s) certified
	Certification date
	Assessment entity
	Nº of certificate renewal
Process Deployment	Motivation to certificate
	Decision maker
	Implementation start
	Implementation finish
	Implementation leader
	Number of components of implementation team
	Profile of implementation team
	Supported by external consultant?
	Main difficulties faced during the implementation.
Implementation methodology	Documents created (procedures, instructions, records) - Quantity?
	Documents created (procedures, instructions, records) – Which?
Benefits and Outcomes	Direct benefits
	Indirect benefits
	Qualitative outcomes
	Quantitative outcomes

3.2 Procedures

Taking as theoretical basis of the above statements, this case study was conducted through interviews and monitoring the activities of the chosen organization. The application of this case study was made in Three-Dimensional Technology Division (DT3D) of the Renato Archer Information Technology Center (CTI), which has a certified quality management system and seeks to continuously improve the efficiency of their system, and quality of offered services and for this reason has been selected for this study.

The case study was developed in DT3D between December 01 and 05, 2014, by a previously trained interviewer, from Center for Strategic Technologies in Health (NUTES) - 3D Technologies Laboratory (LT3D) . The monitoring of activities in the division was made by observation in their sectors, as these are part of the quality management system of this Division.

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After this step, an interview with the director of DT3D was made, according to the above script in table 1, in which it was possible to gather information about the quality management system, from the decision of the ISO 9001: 2008, to the results achieved with the implementation. In sequence, the management consultant, presented all documentation used for ISO implementation, which served as a subsidy for the construction of this case study.

4. CASE STUDY

4.1 Organization History

The organization selected for this case study is the three-dimensional Technologies Division (DT3D), one of units of competency of the Information Technology Renato Archer Center (CTI). The Center is a research institute affiliated to Brazilian Ministry of Science, Technology and Innovation (MCTI) and is engaged in research and development in information technology.

The DT3D Division started to operate in 1997, and since then has been dedicated to research, development and technological applications in various areas of knowledge, supporting the Brazilian industry and medical service providers by means of either internal endeavors or projects in partnership with several universities. Currently, special attention and great effort is put in the medical field by DT3 division, by mean of support to hundreds of hospitals, and services and technology provision to support Brazilian industrial development, as well as pure and industry applied research. These activities are housed in three major programs: the ProMed - focused on research, development and medical applications; the ProInd – dedicated to support the industrial development; and the ProExp - a program focused on the development and broadcast of 3D technologies unconventional applications in industry and scientific experiments. These programs work together as a strategy to seek partnerships in the industry, universities and other R& D centers with the purpose to empower the raise of innovation, scientific publications technological diffusion and relevant services to society (Silva 2013).

4.2 QMS Implementation Process

The Quality Management System Implementation in the organization was made by ISO 9001:2008 in order to gain reliable and demonstrate that their processes and, consequently, its projects and services were performed in order to

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meet the requirements and customer satisfaction;

The implementation process spent 32 months, from mid-April 2009 to November 2011, when the DT3D was granted with certification after audit process conducted by BUREAU VERITAS certification body. The certificate was first valid until November 2014 and is now through its renewal path. To make data collection possible and data analysis feasible to our research team resources, that limited the case study scope to DT3D Research Project and Development (R&D) and services based on three-dimensional technology to the industrial areas, medical service providers and experimental research, including the activities of prototyping, 3D printing, technical evaluation and image reconstruction.

During the construction of this case study, the DT3D was prompt to be re-certified, adding to the certification renewal the Project Development process as a new candidate process to be granted with ISO 9001:2008 certification.

Dr. Jorge Vicente Lopes da Silva, current head of DT3D, made the initial decision to introduce a QMS in the unit. The unit director and four other members, from which three internal staff, an external consultant, composed the implementation team assembled to implement the quality management system.

4.3 Implementation Methodology

We used the turtle diagram to identify each service delivery process, including the activities of the support processes that composes the quality management system and its application. Barnes (1982) states that turtle diagram is a good technique to express process dynamics in a compact view in order to make it easier to understand and further improvement.

One turtle diagram was made for each DT3D processes required to the development of the Quality Management System, such as: Management, Quality Management, Administration, Production, PROIND, PROMED, PROCEXP, Projects, according to the format shown in Figure 1.

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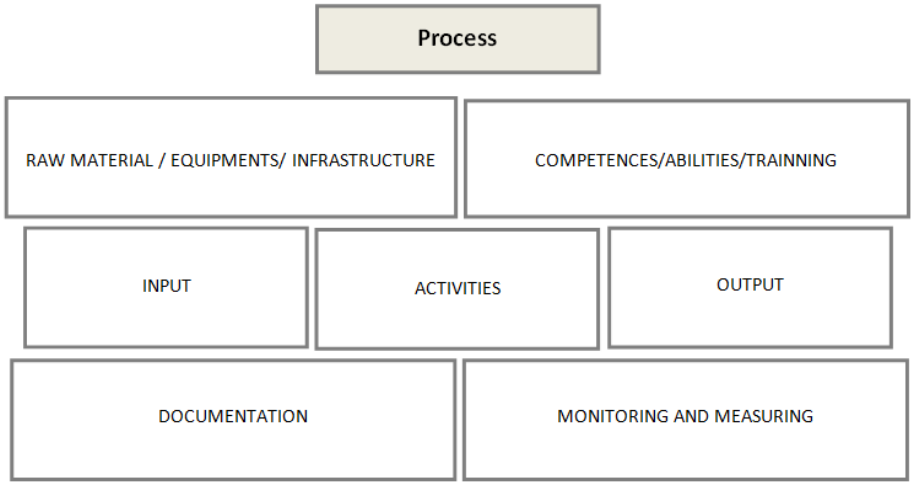

Figure 1 – Diagram displaying the DT3D processes
Source: Quality Manual DT3D

In each item of the diagram, it is described what each process needs to be executed. Special attention is required to items Documentation and Monitoring and Measurement, because in these processes entail the quality procedures (PQ), work instructions (WI) and the quality control documents (QD) that each process needs to be performed as well as the quality registers (QR) that must be made at the end of each procedure.

According to item 4.1 which deals with ISO 9001:2008 general requirements, the organization must: determine the processes that compose the quality management system and its application throughout the organization; determine the execution sequence and interactions of these processes; determine criteria and methods needed to ensure effectiveness in operation and control of these processes; ensure the necessary information and resource provision to support the operation and monitoring of these processes; monitor, measure where applicable and analyze these processes; implement actions that these processes require to achieve planned results and keep in continual improvement.

With this organization the Quality Manual (QM) was described in levels, how would be the structure of the documentation DT3D. Level 1 document is the QM itself, which describes all QMS in its policies, objectives and the Division responsibilities. Level 2 documents were prepared in terms of quality procedures, in each process step is described in detailed instructions. Level 3 documents were

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prepared in form of work instructions and quality control documents in which are as well described in detail and sequentially every activity that must be done to get the result of a particular procedure. In the DT3D case it was determined that IT only would be done when the activity performed was considered critical in the QMS. In level 4 documents the procedures are registered in the form of quality records, which are issued to objectively show that the activities have been actually executed.

According to the item 4.2.1, which refers to generalities of ISO Documentation Requirements 9001:2008, the quality management system documentation shall include: documented statements of a quality policy and quality objectives; a quality manual; documented procedures and records required by this Standard; documents including records, determined by the organization as necessary to ensure the planning, operation and the effective control of its processes.

In compliance with the 9001:2008 standard DT3D has ten documented procedures, which are one DT3D Quality manual, eight quality procedures as required by the standard, and one work instruction for rapid prototyping. There are also six Quality Documents related to the quality objectives and indicators, the responsibility and authority matrix, the personal protective equipment (PPE) , the division professional profile, the specification of critical items such as materials, supplies and services and the failure report processes.

Also according to the standard several quality records have been made, among them master list of QMS documents, minutes of meetings, action and training plans and assessments of their effectiveness, critical analysis of products requests and offers, records of proceedings and check-list of all 3D printers division, record control of production, maintenance reports of 3D printer, control and application of corrective and preventive actions, consolidated indicators and internal audit plan, customer satisfaction survey.

All procedures, records and work instructions are performed by key stakeholders, in digital format, but with manual movement within the division, thus making up a risk, since it can happen any human error in the proceedings. Even with this documentation format, there are no reports of errors, and have been developed over three million cases of success in PRE MED program for surgery and cost reduction.

The DT3D also executes support processes, since this organization is a unit of CTI. They are: DSC - Computer Support Division, the division responsible for

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support and maintenance of IT infrastructure; DINF - Division responsible for take care of DT3D facilities; DSUP - Division of Supplies and Services division responsible for carrying supplies purchases and services when purchased with direct funds from the Federal Budget (Brazilian Federal Government), in these cases it is up to DT3D the technical specification of the purchase of items and after receipt, verify that they are in accordance with specified requirements; HRD - Human Resources Division, the division responsible for the safekeeping documentation related to DT3D employees CTI work contracts; and finally FACTI - a legal entity private, non-profit, Information Technology Foundation with full administrative autonomy dedicated to CTI operations, providing complementary human resources and materials in order to speed up CTI interaction with the market. (SILVA, 2013).

Within DT3D the QMS FACTI takes intermediation between the division and its customers, in what concerns to sale, service and goods acceptance and administration of the resources earned by the division, through the provision of services. FACTI is responsible for purchasing supplies and services, provide skilled labor to complement the team DT3D and keep documentation of these employees. (SILVA, 2013)

Note that the printed prototypes in PROMED program are mostly free, because prototyping services requests come from physicians and / or hospitals in the Brazilian public health system. When request comes from private sources prototypes are made at the request of the physician, for patients who afford prototype. Requests processed in DT3D come from all over the country and even from other countries.

4.4 Benefits and Results achieved with implementation

The DT3D directive board claim that the ISO 9001:2008 - based QMS introduced in the division came to standardize and systematize activities already practiced in their service and products providing routine, since they had been already trying to adopt a systematic management model while they did not have certification yet. With the QMS implementation DT3D has achieving an standardized the entire system according to ISO 9001:2008, made indicators collection and demonstration to Brazilian Ministry of Health straightforward, being able to express more clearly express in numbers and processes every advance that the organization reached. In addition a complete activity map was built, which enabled clear communication and

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comprehension to all levels staff, thus harmonizing the work environment. Standardization of procedures enable also more security to perform DT3D processes activities.

5. CONCLUSIONS

In the course of this study, was described the whole methodology of implementation of the Quality Management System in the 3D Technologies Division of Renato Archer Information Technology Center. As products of the implementation process we had the Quality Manual, a document that defines the scope of the QMS, the Quality Procedures according to the standard, the work instructions for the correct development of activities, quality documents that include the information in the procedures and documents define a standardization of reports and records used by the organization through quality records.

Throughout this study, we can see that the implementation of the QMS was conducted smoothly without causing any harm to the organization. Was efficient, since before the implementation of the standard already intuitively followed a pattern for the proper functioning of the system.We conclude the implementation of ISO 9001:2008 a concrete advance to the DT3D, consolidating and standardizing processes by means of its the Quality Management System.

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